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CENTRAL FAX CENTERApplication No. 10/796,468
Reply to Office Action from 3-13-2006

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REMARKS/DISCUSSION OF ISSUES

Claims 1 - 13 are pending in this application.

Rejections under 35 USC § 103 (a)

Claims 1, 6, and 10 were rejected under 35 USC 103 (a) as being unpatentable over Staylor et al. (US 6,585,685) in view of Bernard et al. (US 2005/0215941).

Claims 2-5, 7-9, and 11-13 were rejected under 35 USC 103 (a) as being unpatentable over Staylor et al. (US 6,585,685) in view of Hogarty et al. (US 2002/0059938).

The rejections of the claims are respectfully traversed.

Response to Arguments

To establish a prima facie case of obviousness, three basic criteria must be met. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vacck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (MPEP 2143).

The Applicant will demonstrate that the combination of the references cited by the Examiner does not teach all the claim limitations and does not result in the claimed invention.

Before arguing the relevance of prior art, it is worth to reiterate what the present invention claims. The present invention teaches detection of the success of the hypodermic jet injection delivery into a body, through measurement of electric resistance between the body and injection device, performing this measurement through the jet of liquid itself during the jet injection drug or vaccine delivery.

The Applicant agrees with the Examiner that Staylor reference discloses a method of delivering drug into patient's body hypodermically as a jet. Neither Staylor reference, nor Bernard reference teach measurements of electrical impedance between patient body and jet injector device, closing the electrical circuit through the jet of liquid, and detecting the change in the electrical resistance during the delivery of the drug into the patient's body as a means to monitor the injection success, i.e. penetration of the jet through the stratum corneum, the outer layer of skin. The disclosure of cited references, in this instance Bernard reference (including the paragraph

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the tissue [0055], through which the current is applied using penetrating electrodes, which is clearly a different technology from the measurement of the impedance between jet injector and body through the jet of liquid during the injection.

Further, Bernard teaches that penetrating electrodes close the circuit through the body, not through the jet as in the instant invention - see Figs. 2, 3, 4, 6, 7, 11C, and 12 in Bernard reference.

Further, Bernard teaches that "the electrodes 308 are retracted within the housing 316 until the treatment is initiated and the needle 12 and electrodes 308 are introduced into the patient." [0115]. Thus the electric current is introduced after the injection, as a means to enhance or perform treatment. In the instant invention, the electric impedance is measured during the injection to ascertain the successful injection. After the jet is delivered, the electric circuit, which was closed through the jet, is disconnected.

Importantly, Bernard teaches that "Since the practice of the present invention requires acute implantation of electrodes and the application of electrical fields in tissue, electrochemically stable electrodes or electrode coatings are desirable" [0119]. Thus the electrodes are inserted in the body. In an Example in Bernard reference, it is specified that "Twenty seconds after completion of the injection, a series of four electrical pulses (200 Volts amplitude, 10 ms duration, 2 Hz frequency) are delivered to the muscle through the implanted electrode array" [0131], making it clear that the electric signal in Bernard reference is applied as a means for patient treatment and is applied post-injection, so that detecting the success of the jet injection and success of the jet penetration through skin by measuring impedance as in the present invention is simply not possible.

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To the contrary, the present invention teaches that the impedance, i.e. electric resistance is measured, which as it is known to these skilled in the art is different from applying electrical current to enhance electroporation or drug mobility in the tissue as taught in Bernard. Moreover, Bernard does not teach a signal detecting successful injection of drug through the skin as taught in the present invention. As embodiments in Bernard reference involve hypodermic needles (Figs. 2 and 6), the success of injection is assured and thus no monitoring of the injection success is needed. The current invention teaches needle-less injection and there are no penetrating needles of any kind.

Thus Bernard reference (as well as Staylor reference) lacks the components of present invention, including means for monitoring electrical impedance, forming an open circuit between patient's body and jet injector, closing the circuit through jet of liquid, measuring and detecting changes in impedance through the jet of liquid during injection. Staylor reference teaches a jet injector, while Bernard reference teaches applying electric current to the tissue through penetrating needles to improve drug delivery and distribution in the tissue via electroporation, after the jet injection or needle-based injection was already completed. The references alone or in combination do not teach passing current through the jet of liquid, nor do they teach impedance monitoring through the jet of liquid.

Thus the combination of Staylor and Bernard references does not result in the claimed invention as claimed in Claims 1, 6, and 10, which should be allowable. The dependent Claims, 2-5, 7-9, 11-13 being dependent upon and further limiting independent Claims 1, 6, and 10, should also be allowable for the same reasons, as well as for additional limitations they contain.

The Examiner has further asserted that Claims 2-5, 7-9, and 11-13 are unpatentable Staylor et al. (US 6,585,685) in view of Fogarty et al. (US 2002/0059938), specifically citing Detailed Description 182 and 229. As was discussed above, the Staylor reference discloses a method of delivering drug into patient's body hypodermically as a jet of liquid. It does not teach means for monitoring electrical impedance, forming an open circuit between patient's body and jet injector, closing the circuit through jet of liquid, measuring and detecting changes in impedance through the jet of liquid during injection. Turning now to the Fogarty reference, this reference teaches a device for accurately marking tissue, including marking a volume of tissue for excision. Fogarty patent application discloses several embodiments of a mechanical device for marking of tissue and has nothing therein related to the transdermal jet injection and monitoring of electrical impedance through jet of liquid during jet injection. The specifically cited by Examiner paragraphs 182 and 229 are descriptive of electronic indicators or feedback alarms to alert a radiologist in positioning the device within specific spatial orientation. Additionally, there is no motivation to combine a jet injector technology with the apparatus for marking tissue for excision. Thus Staylor and Fogarty references alone or in combination lack the components of present invention, including means for

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monitoring electrical impedance, forming an open circuit between patient's body and jet injector, closing the circuit through jet of liquid, measuring and detecting changes in impedance through the jet of liquid during injection. It is concluded that the rejection of Claims 2-5, 7-9, and 11-13 is in error. These dependent claims are further limiting allowable independent Claims 1, 6, and 10, and thus should be allowable for the same reasons, as well as for additional limitations they contain.

Conclusion

The Applicant has demonstrated that the rejection of Claims 1 through 13 is in error. Therefore, it is respectfully suggested that the rejection of independent Claims 1, 6, and 10 under 35 USC 103 (a) is overcome. Dependent Claims 2-5, 7-9, and 11-13, being dependent upon and further limiting independent Claims, should also be allowable for the same reasons, as well as for additional limitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

The Applicant believes that the claims are patentable over the prior art, and that the case is in condition for allowance of all claims therein. Such action is thus respectfully requested.

The Applicant believes that no fees are due in connection with filing of this Office Action reply. The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account 50-3280.

Respectfully submitted:

By:



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